

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION**

This Document Relates to All Actions

MDL No. 2875

Honorable Robert B. Kugler,
District Court Judge

**[PROPOSED] ORDER
GRANTING MOTION TO
SEAL PURSUANT TO
LOCAL CIVIL RULE 5.3**

THIS MATTER having been brought before the Court by Defendants Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Actavis, LLC, and Actavis Pharma, Inc., (collectively, the “Teva Defendants” or “Teva”), on their Motion to Seal Exhibits to Plaintiffs’ Motion for Class Certification of Consumer Economic Loss Claims (Dkt. [1748](#)) Pursuant to Local Civil Rule 5.3(c) (the “Motion to Seal”); and the Court having considered the parties’ submissions, the proposed information to be sealed, and the factors contained in Local Civil Rule 5.3(c)(2); and the Court having further found that the standards set forth therein have been met, the Court hereby **GRANTS** the Motion to Seal in its entirety, making the following Findings of Fact and Conclusions of Law:

FINDINGS OF FACT

1. On June 26, 2019, following extensive negotiations and agreement of the Parties, the Court entered a Confidentiality and Protective Order (the “Protective

Order”) (Dkt. [139](#)) to protect the confidentiality of the parties’ private proprietary information, trade secrets, proprietary scientific information, and other highly sensitive information, both business and personal, exchanged during discovery in this litigation. That Protective Order was subsequently amended via the Amended Confidentiality and Protective Order (the “Amended Protective Order”) and entered in this action by Hon. Thomas I. Vanaskie (Ret.), Special Master, on October 21, 2021 (Dkt. [1661](#)).

2. The Amended Protective Order permits a producing party to safeguard “PROTECTED INFORMATION” by designating a document either “CONFIDENTIAL INFORMATION” and/or “RESTRICTED CONFIDENTIAL INFORMATION” and/or ““RESTRICTED CONFIDENTIAL PBM INFORMATION”

3. Under the Amended Protective Order, “CONFIDENTIAL INFORMATION” includes:

[A]ll information produced by any party in the course of discovery or other proceedings in this case (electronic or otherwise) which is proprietary, trade secret and/or highly sensitive commercial information, and which is believed in good faith by the Producing Party to have the potential, if disclosed, for causing competitive harm to it or giving a competitive advantage to others, and/or which is not publicly available and which a party believes in good faith to be subject to federal, state, or foreign data protection laws or other similar privacy obligations imposed by law. . . .

“RESTRICTED CONFIDENTIAL INFORMATION” includes:

Documents that a Party has designated “RESTRICTED CONFIDENTIAL” in accordance with this Protective Order and includes Documents a Party reasonably believes contain, describe, identify, or refer to highly confidential commercial, business, financial, or competitive information including proprietary manufacturing and production information (including formulation); business and prospective marketing plans; trade secrets; customer lists; pricing, market share, product cost and projected sales data; data relating to mergers and acquisitions; other information of a highly sensitive nature about the Party, which is not publicly available, the disclosure of which could cause the Producing Party competitive harm; and Protected Health Information (“PHI”), as that phrase is defined in the Health Insurance Portability and Accessibility Act of 1996, Pub. L. 104-191 and the regulations promulgated thereunder. . . .

4. Pursuant to the Amended Protective Order, a party may designate a document as “CONFIDENTIAL INFORMATION” or “RESTRICTED CONFIDENTIAL INFORMATION” and, if so, the information may only be used for purposes of this litigation and may only be disclosed to designated persons. Disclosure of information designated as “CONFIDENTIAL INFORMATION” or “RESTRICTED CONFIDENTIAL INFORMATION” other than in accordance with the Amended Protective Order may subject the disclosing party to sanctions.

5. The Amended Protective Order further provides that any documents that a party wishes to file with the Court previously designated as CONFIDENTIAL INFORMATION” or “RESTRICTED CONFIDENTIAL INFORMATION” shall be filed in a manner that preserves the confidentiality of such information. Parties are to attempt to avoid filing materials under seal by working with the Producing Party to create non-confidential, redacted, or excerpted pages of materials containing

PROTECTED INFORMATION to attach to filings. The Amended Protective Order further directs the parties to confer to see if they can agree upon the non-confidential portions of the material that can be attached to the filing and, if an agreement cannot be reached, requires the designating party to file a motion to seal the materials containing PROTECTED INFORMATION pursuant to Local Rule 5.3(c).

6. The Teva Defendants have produced over 225,000 documents in this action with confidentiality designations following the designations specified in the Protective Order and Amended Protective Order. On or around June 18, 2021, Plaintiffs' counsel challenged the Teva Defendants' confidentiality designations for 126 documents. After meeting and conferring with plaintiffs' counsel on several occasions, Teva ultimately agreed to de-designate all but 26 of the contested documents. The remaining 26 documents were the subject of a discovery hearing heard by Hon. Thomas I. Vanaskie (Ret.), on September 13, 2021. *See* Dkt. [1561](#).¹

7. On or around September 6, 2022, Plaintiffs challenged the confidentiality designations of 19 Exhibits that were attached to the Parties' briefing on class certification. After numerous rounds of meeting and conferring, the Teva Defendants agreed to de-designate, or agreed to appropriate redactions, on all but 6 documents which were filed as Exhibits to Plaintiffs' Motion for Class Certification

¹ One of the 26 documents addressed by Judge Vanaskie in September 2021, which was ordered to remain confidential, is at issue again here, TEVA-MDL2875-00400391 to TEVA-MDL2875-0040000 (attached as **Ex. 90** to Dkt. [1748](#)).

of Consumer Economic Loss Claims (Dkt. [1748](#)) on November 10, 2021. The Teva Defendants have moved to seal the following documents designated as “CONFIDENTIAL INFORMATION” and/or “RESTRICTED CONFIDENTIAL INFORMATION”, pursuant to the Amended Protective Order and Local Rule 5.3:

- TEVA-MDL2875-00049024 (attached as **Exs. 16 and 67** to Dkt. [1748](#))
- TEVA-MDL2875-00549883 (attached as **Ex. 66** to Dkt. [1748](#))
- TEVA-MDL2875-00020519 (attached as **Ex. 72** to Dkt. [1748](#))
- TEVA-MDL2875-00522655 to TEVA-MDL2875-00522660
(attached as **Ex. 88** to Dkt. [1748](#))
- TEVA-MDL2875-00400391 to TEVA-MDL2875-0040000 (attached as **Ex. 90** to Dkt. [1748](#)) (previously ordered to remain confidential at September 2021 discovery hearing)
- TEVA-MDL2875-00042885 to TEVA-MDL2875-00042887
(attached as **Ex. 97** to Dkt. [1748](#))

8. These documents include internal investigation reports and other documents and communications that (a) provide information about the Teva Defendants’ internal reporting and investigative processes; (b) are competitively sensitive as they comment on the Teva Defendants’ evaluation of various suppliers; (c) provide information of the Teva Defendants’ internal toxicology and risk assessment processes; and/or (d) provide information about the Teva Defendants’

internal reporting and audit processes. The above-referenced documents likewise contain non-public, highly sensitive commercial information, which is believed in good faith by the Teva Defendants to have the potential, if publicly disclosed, to cause significant competitive harm to the Teva Defendants and competitive advantage to their direct competitors. None of the documents were disclosed to third parties prior to this litigation.

CONCLUSIONS OF LAW

9. It is well-established that there is a “common law public right of access to judicial proceedings and records.” *In re Cendant Corp.*, 260 F.3d 183, 192 (3d Cir. 2001). This is consistent with well-established precedent, based on First Amendment considerations and the common law right of access to judicial records, that documents filed with the court and judicial proceedings are open to the public. *See Nixon v. Warner Communications, Inc.*, 435 U.S. 589, 597, 98 S. Ct. 1306, 55 L. Ed. 2d 570 (1978).

10. In order to overcome this presumption of a public right of access, the movant must demonstrate that “good cause” exists for the protection of the material at issue. *See Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994). Good cause exists when a party makes a particularized showing that disclosure will cause a “clearly defined and serious injury to the party seeking closure.” *Pansy*, 23 F.3d at 786 (quoting *Publicker Indus., Inc. v. Cohen*, 733 F.2d

1059, 1071 (3d Cir. 1984)). The claimed injury must be specifically stated because “[b]road allegations of harm, unsubstantiated by specific examples or articulated reasoning,’ do not support a good cause showing.” *Id.* at 786 (quoting *Cipollone v. Liggett Group, Inc.*, 785 F.2d 1108, 1121 (3d Cir. 1986)).

11. The sealing of confidential documents and information is an accepted practice in the District of New Jersey. *In re Gabapentin Patent Litig.*, 312 F. Supp. 2d 653, 653 (D.N.J. 2004). “Every court has supervisory power over its own records and files, and access has been denied where court files might have become a vehicle for improper purposes.” *Littlejohn*, 851 F.2d at 678 (quoting *Nixon v. Warner Commc’ns, Inc.*, 435 U.S. 589, 598 (1978)).

12. Under Local Rule 5.3(c), material may be filed and maintained under seal upon a showing of good cause. *See* L. CIV. R. 5.3(c); *Vista India, Inc. v. Raaga, LLC*, No. 07-cv- 1262, 2008 WL 834399, at *3 (D.N.J. Mar. 27, 2008). The moving party must show that the following factors weigh in favor of sealing the information at issue: (1) the nature of the materials or proceedings at issue; (2) the legitimate private or public interest which warrants the relief sought; (3) the clearly defined and serious injury that would result if the relief sought is not granted; and (4) why a less restrictive alternative to the relief sought is not available. Local Rule 5.3(c)(3). This Court has discretion in balancing the factors for and against access to court documents. *See Pansy*, 23 F.3d at 781.

13. Factors weighing in favor of confidentiality are: (1) the information to be protected includes genuinely confidential information such as proprietary materials, or information that could give unfair advantage to a competitor; (2) the documents were produced under the auspices of an existing confidentiality order upon which the parties relied; (3) the materials are not subject to freedom of information laws or statutes requiring disclosure of public documents; and (4) the party to benefit from the order is a private entity, not a public official seeking protection from “legitimate public scrutiny.” *Pansy*, 23 F.3d at 788-91. The scale is tipped in favor of confidentiality where the parties relied on a prior confidentiality order. *See, e.g., Rutigliano v. Appleton Papers, Inc.*, No. 90-1432, 2000 WL 1705152 at *5 (D.N.J. Oct. 6, 2000) (public disclosure in product liability action should not be compelled where defendant produced material in reliance on a confidentiality order).

14. The Court finds that there is good cause to seal the documents that are the subject of the instant motion.

15. The Teva Defendants have a legitimate interest in maintaining the confidentiality of the commercially sensitive information at issue. *See, e.g., Goldenberg v. Indel*, Civil Action No. 09-5202 (JBS/AMD), 2012 WL 15909, at *9 (D.N.J. Jan. 3, 2012) (finding legitimate privacy interest in preventing disclosure of confidential business agreements, private email exchanges discussing the ways in

which entities calculated certain fees, and other commercially sensitive documents); *Congo, LLC v. Revcontent, LLC*, Civil Action No. 16-401-MAS, 2016 WL 3751613 (D.N.J. July 13, 2016) (granting motion to seal confidential business information related to interactions with company's clients, internal financial business information, and internal details of the parties' businesses). Upon weighing the relevant factors, Teva's interest in maintaining the confidentiality of the subject documents and avoiding the irreparable competitive harm that would result if the documents were disclosed, overcomes the presumption of the public right of access.

16. The materials Teva seeks to protect from disclosure are all internal, non-public, highly sensitive documents produced in this action pursuant to a confidentiality and protective order. *See Goldenberg v. Indel*, 2012 U.S. Dist. LEXIS 479, 2012 WL 15909, at *7 (D.N.J. Jan. 3, 2012) (“[T]he Court finds it important to note the existence of the protective order and the parties’ agreement that documents falling into these categories may properly be designated as confidential and should be protected from public disclosure beyond the confines of the Confidentiality Order during the discovery period.”). Those documents provide insight into Teva’s business strategies and internal processes as it relates to the investigation, auditing, reporting, and preventive action undertaken by Teva in response to the presence of impurities in pharmaceuticals that it manufactures. Disclosure of this strategic information to Teva’s competitors, in the highly competitive generic pharmaceutical

space, would cause irreparable competitive harm to the Teva Defendants that cannot be avoided absent maintaining the documents under seal.

17. TEVA-MDL2875-00049024 (attached as **Exs. 16 and 67** to Dkt. [1748](#)), Investigation Report gDR# 1336473 (July 2, 2019), provides information concerning Teva's internal reporting, investigative processes, and corrective and preventive actions taken related to the NDMA and NDEA impurities discovered in Valsartan API manufactured by a Teva supplier. This document also provides comments on Teva's evaluation of a supplier, which is competitively sensitive. The disclosure of this document would result in direct competitive harm to Teva by allowing its competitors valuable information into Teva's internal processes for handling investigations, internal reporting, and corrective and preventive actions. There is no alternative practicable to prevent this harm to Teva. Therefore, Teva's motion is **GRANTED** as to this document.

18. TEVA-MDL2875-00549883 (attached as **Ex. 66** to Dkt. [1748](#)), Global Quality Report: 2018-GQ-020-1v1, is a similar internal investigation report that provides information about Teva's internal processes and strategies for corrective and preventive actions related to the NDMA and NDEA impurities discovered in Valsartan API manufactured by a Teva supplier. The disclosure of this document would cause irreparable harm to Teva by providing its competitors with direct insight into Teva's internal processes for investigating, evaluating, correcting, and

mitigating the presence of impurities in medications manufactured by Teva. There is no alternative practicable to prevent the competitive harm that would result to Teva. Teva's motion is therefore **GRANTED** as to this document.

19. TEVA-MDL2875-00020519 (attached as **Ex. 72** to Dkt. [1748](#)) is an internal communication that reveals Teva's internal toxicology and risk assessment processes related to the presence of NDMA in Valsartan API. The disclosure of this document would reveal the thought processes of Teva's leadership and allow Teva's competitors to identify, replicate, and undercut Teva's internal processes and business strategies related to toxicology and risk assessment, thereby causing significant competitive harm. There is no alternative practicable to prevent the competitive harm that would result to Teva. Teva's motion is **GRANTED** as to this document.

20. The internal communication TEVA-MDL2875-00522655 to TEVA-MDL2875-00522660 (attached as **Ex. 88** to Dkt. [1748](#)) discusses preparation of an audit report and provides information about Teva's internal reporting and audit processes. The disclosure of this document would likewise cause irreparable harm to Teva by providing its competitors with the internal thought processes of Teva leadership concerning an internal audit as well as Teva's internal reporting processes. This would cause Teva significant competitive harm. There is no

alternative practicable to prevent the competitive harm that would result to Teva. Teva's motion is **GRANTED** as to this document.

21. The internal communication TEVA-MDL2875-00400391 to TEVA-MDL2875-0040000 (attached as **Ex. 90** to Dkt. [1748](#)) discusses preparation of an audit report and provides information about the Teva Defendants' internal reporting and audit processes. This document was previously ordered to remain confidential at the September 13, 2021 discovery hearing in this action. Because the disclosure of this document would still cause irreparable competitive harm to Teva by revealing the internal thought processes of Teva leadership concerning internal reporting and audit processes, the document will remain sealed. Teva's motion is **GRANTED** as to this document.

22. The internal communication TEVA-MDL2875-00042885 to TEVA-MDL2875-00042887 (attached as **Ex. 97** to Dkt. [1748](#)) discusses the internal assessments of processes in place at Teva for toxicology and risk assessments. The disclosure of this document would cause irreparable harm to Teva by providing its competitors with the internal thought processes of Teva leadership concerning the processes in place for toxicology and risk assessment, as well as evaluation of corrective and preventive action in response to the presence of nitrosamines in Valsartan. This would cause Teva significant competitive harm. There is no

alternative practicable to prevent the competitive harm that would result to Teva.

Teva's motion is **GRANTED** as to this document.

SO ORDERED this ____ day of _____, 2023

Hon. Thomas I. Vanaskie, (Ret.)
Special Master